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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,550	11/05/2003	Theo T. Nikiforov	100/07934	1067
21569	7590	05/13/2005		EXAMINER
CALIPER LIFE SCIENCES, INC. 605 FAIRCHILD DRIVE MOUNTAIN VIEW, CA 94043-2234				CALAMITA, HEATHER
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 05/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/701,550	NIKIFOROV, THEO T.
	Examiner Heather G. Calamita, Ph.D.	Art Unit 1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 15 February 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 10-16 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-9 and 17-28 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 1/10/05
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

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## DETAILED ACTION

### *Status of Application, Amendments, and/or Claims*

1. Amendments of February 15, 2005 have been received and entered in full. Claims 1-28 are pending. Claims 1-9 and 17-28 are under examination. Any objections and rejections not reiterated below are hereby withdrawn.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 17-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number'' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

All of the current claims are broadly drawn to a genus of molecules having multivalent metal cations associated therewith which are different from those disclosed in the specification. The genus includes variants for which no written description is provided in the specification. This large genus is

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represented in the specification by only the particularly named amino acids (specifically polylysine and polyarginine). Thus, applicant has express possession of only two particular molecules which are associated with multivalent cations in a genus which comprises hundreds of millions of different possibilities. Here, no common elements or attributes of the molecules are disclosed. No structural limitations or requirements which provide guidance on the identification of molecules which meet the functional limitations are provided.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

The current situation is a definition of the compound solely by its functional utility, as a molecule having multivalent cations associated with it, without any definition of the particular molecules claimed.

In the instant application, certain specific molecules are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any molecules having multivalent metal cations associated with them other than those expressly disclosed which comprise polylysine and polyarginine.. Therefore, the claims fail to meet the written description requirement by encompassing molecules which are not described in the specification.

*Response to Arguments*

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3. Applicants' arguments filed February 15, 2005, have been fully considered but they are not persuasive. Applicants assert the issue of whether claims 1-9 and 17-28 meet the written description requirement has been settled by litigation involving patents to which this application claims direct priority. Applicants submitted a claim construction order from the United States District Court for the Northern District of California, Case NO. C 02-01837 indicating how the court interpreted the scope of the asserted claims. Particularly, the Court interpreted the meaning of the term "binding component comprising multivalent metal ions associated therewith" to mean "a polycationic component that includes but is not limited to metallic ions, which are metal atoms or groups of atoms, bearing multiple electrical charges and that is of sufficient size to cause a change in the level of fluorescence polarization upon its association with a smaller molecule when it binds to it in a non-specific, charge-dependent manner." Applicant further argues the Court's claim construction makes it clear that the specification makes it clear that the term "molecular having multivalent metal cations associated therewith" does not refer to an arbitrarily large genus.

With respect to Applicants' arguments, the Court's Claim Construction Order was directed to the matter of infringement, not to the matter of written description, and the Court's interpretation of the claims with respect to infringement is irrelevant to the current written description rejections. Additionally, the standards of claim interpretation used by the Court are distinct from those of the USPTO. The standard adhered to by the USPTO requires the claims must be interpreted as broadly as their terms reasonably allow.

"Applicants' interests are not impaired since they are not foreclosed from obtaining appropriate coverage for their invention with express claim language. An applicant's ability to amend his claims to avoid cited prior art distinguish proceedings before the PTO from proceedings in federal district courts on issued patents. When an application is pending in the PTO, the applicant has the ability to correct errors in claim language and adjust the scope of claim protection as needed."; *In Re Zletz*, 893 F.2d at 321, as reiterated in 2004, with *In Re American Academy of Science 1 Center*, 70 USPQ 2d 1827.

Finally, the Claim Construction Order from the District Court was not a final judgment and therefore is given no deference by the USPTO, in accordance with MPEP 2286 which states,

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"Thus, while the Office may accord deference to factual findings made by the court, the determination of whether a substantial new question of patentability exists will be made independently of the court's decision on validity as it is not controlling on the Office. A non-final holding of claim invalidity or unenforceability will not be controlling on the question of whether a substantial new question of patentability is present."

While this passage of the MPEP refers to re-examination of an application, it applies to initial examination as well. For all of the aforementioned reasons, the Examiner is not persuaded to withdraw the written description rejections of claims 1-9 and 17-28.

*Conclusion*

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

*Correspondence*

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

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Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

hgc

JEFFREY FREDMAN  
PRIMARY EXAMINER

5/16/05